

GIBSON, DUNN & CRUTCHER LLP
G. CHARLES NIERLICH, SBN 196611
gnierlich@gibsondunn.com
TIMOTHY LOOSE, SBN 241037
tloose@gibsondunn.com
MATTHEW L. BERDE, SBN 260615
mberde@gibsondunn.com
555 Mission Street, Suite 3000
San Francisco, CA 94105-2933
Telephone: 415.393.8200
Fax: 415.393.8306

Attorneys for Defendant
CYTOSPORT, INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

CLAIRE DELACRUZ, individually, and on
behalf of other members of the general public
similarly situated,

Plaintiff,

v.

CYTOSPORT, INC., a California Corporation,

Defendant.

CASE NO. 4:11-cv-03532-CW

**DEFENDANT CYTOSPORT, INC.'S
NOTICE OF MOTION AND MOTION
TO DISMISS PLAINTIFF'S SECOND
AMENDED COMPLAINT FOR
FAILURE TO STATE A CLAIM AND
LACK OF STANDING, OR, IN THE
ALTERNATIVE, TO STAY ALL
CLAIMS**

[Fed. R. Civ. P. 8(a)(2), 9(b), 12(b)(1),
12(b)(6)]

Hearing Date: June 7, 2012
Hearing Time: 2:00 p.m.
Location: Courtroom 2, 4th Floor
Judge: Hon. Claudia Wilken

Trial Date: None Set

TABLE OF CONTENTS

	<u>Page</u>
I. INTRODUCTION	1
II. FACTUAL BACKGROUND	2
III. ARGUMENT	5
A. Legal Standard	5
B. Plaintiff Has Failed To Plead An Actionable Misrepresentation Under The UCL, FAL, CLRA, Or Common Law	6
1. The 14 Ounce RTD Bottle Contains No False Or Misleading Statement.....	7
a. “Good Carbohydrates”	8
b. “Healthy, Sustained Energy”	9
c. “25g PROTEIN” And “Protein Nutrition Shake”	10
d. “Healthy Fats”	10
e. Website And Television Statements Regarding 14 Ounce RTD	10
2. The Label For Muscle Milk® Bars Makes No False Or Misleading Statement.....	11
a. “25g PROTEIN for Healthy, Sustained Energy”	11
b. Palm Oil	12
c. “Healthy, Sustained Energy” Advertisement On CytoSport’s Website.....	13
C. Plaintiff Cannot Rely On Federal Food Labeling Regulations To Save Her Claims .	13
1. Plaintiff’s Allegations Concerning Technical Violations Of FDA Regulations Cannot Support Any Of Her Misrepresentation Claims	14
2. CytoSport Has Not Made Improper Nutrient Content Claims.....	17
3. The Primary Jurisdiction Doctrine Requires Dismissal Or A Stay	19
4. Plaintiff Should Not Be Allowed To Add Allegations That Rely On The FDCA And Its Regulations	20
D. Plaintiff Has Not Adequately Alleged Reliance On The New Advertising Statements	21
IV. CONCLUSION.....	25

TABLE OF AUTHORITIES

	<u>Page</u>
Cases	
<i>Aaronson v. Vital Pharm., Inc.</i> , 2010 WL 625337 (S.D. Cal. Feb. 17, 2010).....	19
<i>Ashcroft v. Iqbal</i> , 556 U.S. 662 (2009).....	5, 6, 15, 23
<i>Bardin v. Daimlerchrysler Corp.</i> , 136 Cal. App. 4th 1255 (2006)	7
<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544 (2007).....	5, 22, 23
<i>Bibb v. Navajo Freight Lines, Inc.</i> , 359 U.S. 520 (1959).....	20
<i>Buckman Co. v. Plaintiff's Legal Comm.</i> , 531 U.S. 341 (2001).....	19
<i>Cattie v. Wal-Mart Stores, Inc.</i> , 504 F. Supp. 2d 939 (S.D. Cal. 2007).....	23
<i>Century Sur. Co. v. Crosby Ins., Inc.</i> , 124 Cal. App. 4th 116 (2004)	6
<i>Clark v. Time Warner Cable</i> , 523 F.3d 1110 (9th Cir. 2008)	19
<i>Freeman v. Time, Inc.</i> , 68 F.3d 285 (9th Cir. 1995)	6
<i>Fraker v. KFC Corp.</i> , No. 06-1284, 2007 WL 1296571, (S.D. Cal. Apr. 30, 2007)	20
<i>Gade v. Nat'l Solid Wastes Mgmt. Ass'n</i> , 505 U.S. 88 (1992).....	20
<i>Herrington v. Johnson & Johnson Consumer Co.</i> , No. C 09-1597 CW, 2010 WL 3448531 (N.D. Cal. Sept. 1, 2010).....	6, 7, 22
<i>In re Actimmune Marketing Litig.</i> , 2009 WL 3740648 (N.D. Cal. Nov. 6, 2009)	22, 24
<i>In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.</i> , No. MDL 08-1934, 2009 WL 1703285 (C.D. Cal. Jun. 17, 2009).....	20
<i>In re Farm Raised Salmon Cases</i> , 42 Cal. 4th 1077 (2008)	20
<i>In re Tobacco II Cases</i> , 46 Cal. 4th 298 (2009)	22, 24
<i>Int'l Dairy Foods Ass'n v. Amestoy</i> , 92 F.3d 67 (2d Cir. 1996)	18
<i>Kearns v. Ford Motor Co.</i> , 567 F.3d 1120 (9th Cir. 2009)	6, 23
<i>Lavie v. Proctor & Gamble Co.</i> , 105 Cal. App. 4th, 496 (2003)	6, 8

1	<i>Mason v. Coca-Cola Co.</i> ,	
2	774 F. Supp. 2d 699 (D.N.J. 2011)	16
3	<i>Meyer v. Sprint Spectrum, L.P.</i> ,	
4	45 Cal. 4th 634 (2009)	22
5	<i>Navarro v. Block</i> ,	
6	250 F.3d 729 (9th Cir. 2001)	5
7	<i>New Hampshire v. Maine</i> ,	
8	532 U.S. 742 (2001)	21
9	<i>Parrino v. FHP, Inc.</i> ,	
10	146 F.3d 699 (9th Cir. 1998)	8
11	<i>Pearson v. Shalala</i> ,	
12	164 F.3d 650 (D.C. Cir. 1999)	16
13	<i>Physicians Comm. for Responsible Medicine v. General Mills, Inc.</i> ,	
14	No. 1:05cv958, 2006 WL 3487651 (E.D. Va. Nov. 30, 2006)	20
15	<i>Robinson Helicopter Co., Inc. v. Dana Corp.</i> ,	
16	34 Cal. 4th 979 (2004)	6
17	<i>Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.</i> ,	
18	902 F.2d 222 (3d. Cir. 1990)	16
19	<i>Sugawara v. Pepsico, Inc.</i> ,	
20	2009 WL 1439115 (E.D. Cal. May 21, 2009)	7
21	<i>Summit Tech., Inc. v. High-Line Med. Instruments Co.</i> ,	
22	933 F. Supp. 918 (C.D. Cal. 1996)	20
23	<i>United States v. Ibrahim</i> ,	
24	522 F.3d 1002 (9th Cir. 2008)	21
25	<i>United States v. Phila. Nat'l Bank</i> ,	
26	374 U.S. 321 (1963)	19
27	<i>United States v. W. Pac. R.R. Co.</i> ,	
28	352 U.S. 59 (1956)	20
	<i>Vess v. Ciba-Geigy Corp. USA</i> ,	
	317 F.3d 1097 (9th Cir. 2003)	6, 7, 10
	<i>Williams v. Gerber Prod. Co.</i> ,	
	552 F.3d 934 (9th Cir. 2008)	6, 10
	<i>Yumul v. Smart Balance, Inc.</i> ,	
	733 F. Supp. 2d 1117 (C.D. Cal. 2010)	16
	Statutes	
	21 U.S.C. § 337(a)	19, 20
	21 U.S.C. § 337(b)(2)	20
	21 U.S.C. § 343(a)	14, 17
	21 U.S.C. § 343(d)	14
	21 U.S.C. § 343(e)	14
	21 U.S.C. § 343(r)(1)(A)	14
	21 U.S.C. § 343(r)(2)(A)	14

Rules

Fed. R. Civ. P. 9(b) 6

Regulations

21 C.F.R. § 10.25(b) 19

21 C.F.R. § 101.9(c)(2) 13

21 C.F.R. § 101.13(a) 14

21 C.F.R. § 101.13(b)(1) 14

21 C.F.R. § 101.13(b)(2) 15, 18

21 C.F.R. § 101.13(i) 15

21 C.F.R. § 101.65(d)(1) 15, 17, 18

21 C.F.R. § 101.65(d)(2) 15

21 C.F.R. § 172.800 8

21 C.F.R. § 172.831 8

58 Fed. Reg. 2302 17

NOTICE OF MOTION AND MOTION

PLEASE TAKE NOTICE that on June 7, 2012, at 2:00 p.m., in Courtroom 2 of the above-captioned court, located at 1301 Clay Street, Oakland, California 94612, or as soon thereafter as may be heard, Defendant CytoSport, Inc. (“CytoSport”) will, and hereby does, move this Court for an order under Federal Rules of Civil Procedure 8(a)(2), 9(b), 12(b)(1), and 12(b)(6), dismissing all of the claims and causes of action contained in the Second Amended Complaint filed in this action by Plaintiff Claire Delacruz, or, in the alternative, dismissing or staying all claims pursuant to the primary jurisdiction doctrine.

This Motion is based on this Notice, the following Memorandum of Points and Authorities, all matters of which judicial notice may be taken, the Declaration Of G. Charles Nierlich In Support of Defendant CytoSport, Inc.’s Motion To Dismiss Plaintiff’s Second Amended Complaint For Failure To State A Claim (“Nierlich Decl.”), the papers and pleadings on file herein, and on such additional papers and arguments as may be presented at or before the hearing of this matter.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

In her First Amended Complaint (“1AC”), Plaintiff broadly asserted that CytoSport made various supposedly false and misleading statements in the advertising and labeling of certain Muscle Milk® products. In an Order dated April 11, 2012, this Court dismissed the 1AC with respect to all of these purported misstatements except for one: the statement “healthy fats” on the back of the label for CytoSport’s 14 ounce Muscle Milk® ready-to-drink (“RTD”) shake, buttressed by the statement on that product’s label that it is a “nutritional shake.” Order Granting in Part and Denying in Part CytoSport’s Motion to Dismiss Plaintiff’s First Amended Complaint, Dkt. 34 at 12:24-13:9. The Court granted Plaintiff leave to amend, “if she [wa]s able truthfully to do so without contradicting the allegations in her original complaint.” *Id.* at 27:13-14.

In her Second Amended Complaint (“2AC”), Plaintiff repeats many of the same allegations from the 1AC that this Court already dismissed. She once again claims that the phrase “healthy, sustained energy” on the labels of Muscle Milk® products (and on its website) is false and misleading even though the Court previously rejected this assertion. The Court also rejected

1 Plaintiff's attempt to analogize Muscle Milk® products to a donut; nonetheless, she now attempts to
 2 analogize the Muscle Milk® Bars to Snickers® bars as the supposed basis for her claim that the Bars
 3 are misleadingly marketed as healthy. And, Plaintiff repeats, almost verbatim, her same allegations
 4 concerning the presence of palm oil in Muscle Milk® Bars that the Court previously dismissed.
 5 None of these recycled allegations are any more actionable now than before.

6 Plaintiff also adds several new allegations. Most notably, while Plaintiff once disavowed any
 7 reliance on the Federal Food and Drug Administration's food labeling regulations, she now embraces
 8 them and alleges several violations of those regulations that are carbon copies of the allegations made
 9 in a warning letter to CytoSport from a staff member of the FDA's San Francisco field office.¹ But
 10 the advertising statements that Plaintiff attacks do not violate those regulations in the first place.
 11 Even if Plaintiff were to establish a technical violation of some FDA regulations, that alleged non-
 12 compliance would not necessarily make the product label misleading or likely to deceive a reasonable
 13 consumer. And if the Court should determine that any of Plaintiff's claims based on FDA regulations
 14 remain viable, CytoSport renews its request that this matter be stayed or dismissed based on the
 15 FDA's primary jurisdiction, as these claims require detailed construction of several sections of Title
 16 21 of the Code of Federal Regulations, which encompass some 4,000 pages and fill nine full volumes
 17 of regulations promulgated, interpreted, and enforced by the FDA.

18 In short, the 2AC is an amalgam of rejected and rehashed allegations from the 1AC,
 19 combined with allegations of regulatory violations that Plaintiff previously abandoned and, in any
 20 event, do not support her claims. The 2AC does no more to state a viable claim than the 1AC.

21 II. FACTUAL BACKGROUND

22 Based in Benicia, CytoSport manufactures a line of protein products under the Muscle Milk®
 23 brand name. 2AC at ¶¶ 1, 12, 22, 33. Muscle Milk® is available in multiple forms, including ready-
 24 to-drink ("RTD") beverages and nutrition bars. *Id.* at ¶ 1. Plaintiff filed the 1AC broadly asserting
 25 that CytoSport made various supposedly false and misleading statements in the advertising and
 26 labeling of its 14 ounce and 17 ounce Muscle Milk® RTD products and its Bar. 1AC at ¶¶ 1-5.

27
 28

¹ A copy of this letter is attached as Exhibit A to the Nierlich Decl.

Specifically, Plaintiff challenged the placement of the words “Healthy, Sustained Energy” on the back of the 17 ounce Muscle Milk® RTD package (1AC at ¶ 14), the terms “healthy fats” and “good carbohydrates” on the packaging of the 14 ounce Muscle Milk® RTD bottle (*id.* at ¶¶ 17-18)², the use of the words “healthy, sustained energy” in the phrase “25g protein for healthy, sustained energy,” and the phrase “0g Trans Fat” on the wrapper of the Muscle Milk® Bar (*id.* at ¶¶ 32-34). Plaintiff did not challenge the use of the words “Healthy, Sustained Energy” on the 14 ounce Muscle Milk® RTD package. Plaintiff also targeted the palm oil content of Muscle Milk® Bars, CytoSport’s humorous advertising slogans for Muscle Milk® such as “From Invisible To OMG!” and “Go From Cover It Up To Take It Off,” statements on CytoSport’s website, including the words “Healthy, Sustained Energy” in the website’s header, and statements that Muscle Milk® is an “ideal” product for various people. *Id.* at ¶¶ 19, 22, 28-31.

On October 17, 2011, CytoSport moved to dismiss the 1AC. *See* Defendant CytoSport, Inc.’s Notice of Motion and Motion to Dismiss Plaintiff’s First Amended Complaint for Failure to State a Claim and Lack of Standing, or, in the Alternative, to Stay all Claims, Dkt. 14. This Court granted the motion except to the extent it challenged the “healthy fats” statement on the 14 ounce Muscle Milk® RTD label, along with the statement “nutritional shake” on the label, which “contributes to a sufficient claim of deceptive product labeling.” Dkt. 34 at 12:24-13:9. The Court rejected the 1AC’s allegation that CytoSport’s use of “Healthy, Sustained Energy” on the packaging of the 17 ounce RTD and the Bars, and “0g Trans Fat” on the Bars, were misrepresentations. *Id.* at 13:24-14:20. The Court found the marketing slogans challenged by Plaintiff—such as “Go from cover it up to take it off” and “From invisible to OMG!”—to be non-actionable puffery. *Id.* at 14:21-28. The claim “ideal nutritional choice . . .” was also deemed non-actionable. *Id.* at 14:21-15:3.

The Court also ruled that Plaintiff failed to allege that CytoSport’s advertising of Muscle Milk® “approached the longevity and pervasiveness of the marketing at issue in *Tobacco II*” and also failed to plead reliance on CytoSport’s “long-term advertising campaign,” as Plaintiff did not plead

² In the 1AC, Plaintiff never alleged why the term “good carbohydrates” was false or misleading.

that she “actually saw and relied upon any particular statements in Defendant’s advertising.” *Id.* at 18:17-27. The Court also rejected Plaintiff’s alleged reliance on CytoSport’s website. *Id.* at 19:1-3.

Plaintiff was given leave to amend so that she could “remedy[] the defects addressed [in the Court’s Order] if she [wa]s able truthfully to do so without contradicting the allegations in her original complaint.” Dkt. 34 at 27:12-14.

In the 2AC, Plaintiff again alleges that CytoSport has made “false, misleading, deceptive, and unfair” representations that Muscle Milk® products are “healthy” and “provide[] a wide range of significant nutritional benefits.” 2AC at ¶¶ 5, 6. The 2AC focuses on statements on the labels of the 14 ounce Muscle Milk® RTD and Muscle Milk® Bars, and some related statements concerning those products on CytoSport’s website. Specifically, the 2AC alleges the following:

Muscle Milk® 14 ounce RTD

- The “claim ‘Healthy, Sustained Energy’ in connection with the statements ‘Protein Nutrition Shake’ and ‘25g PROTEIN’” on the label is misleading. 2AC at ¶ 20, 43, 58. (As Plaintiff acknowledges, however, the label for the 14 ounce RTD that included the words “Healthy, Sustained Energy” was “phased out of production[] starting in Feb[ruary] 2011” and was replaced by a label that does not include this phrase. *Id.* at ¶ 22.)
- The phrase “healthy fats” on the back of the label is false and misleading. *Id.* at ¶¶ 22-24.
- The phrase “good carbohydrates” on the back of the label is false and misleading. *Id.* at ¶¶ 22-23, 25.
- The “claims that Muscle Milk® Ready-To-Drink (RTD) ‘promotes healthy sustained energy,’ and that it provides ‘healthy fats’ and ‘good carbohydrates’” on CytoSport’s website for Muscle Milk® 14 ounce RTD somehow “compound” other false and misleading statements. *Id.* at ¶¶ 27-28.
- Television commercials for Muscle Milk® 14 ounce RTD that allegedly “feature images of the label” of the product and thus “republish the false and misleading claim ‘Healthy, Sustained Energy’ in connection with the statements ‘Protein Nutrition Shake,’ ‘25g PROTEIN,’ and ‘It’s powerful protein’” also “compound” other false and misleading statements. *Id.* at ¶¶ 30-31.

Muscle Milk® Bars

- The statement “25g PROTEIN for Healthy, Sustained Energy” on the wrapper of the Muscle Milk® Bar is false or misleading. *Id.* at ¶¶ 32-35.
- That Muscle Milk® Bars are unhealthy because they contain fractionated palm kernel oil. *Id.* at ¶¶ 37-39.
- That the CytoSport website states, with respect to Muscle Milk® Bars, that “‘there’s no question [you’re] getting a nutritious snack,’ and that ‘Muscle Milk Bars are loaded with 25

grams of high-quality muscle source protein,’ and ‘Muscle Milk Bars deliver . . . healthy sustained energy.’” *Id.* at ¶¶ 41-42.

- The statement “0g Trans Fat” is false and misleading. *Id.* at ¶¶ 62-64.
- That the nutritional information on the Vanilla Toffee Crunch Muscle Milk® Bar is incorrect because that product “actually contain[s] 13 grams of total fat and 10 grams of saturated fat, not the 10 grams of total fat and 8 grams of saturated fat on the label.” *Id.* at ¶ 35.

Plaintiff alleges that for “approximately six continuous months before the filing of the initial Complaint in this action,” she “regularly purchased and consumed” Muscle Milk® RTD and Bars. Dkt. 34 at ¶ 73. The 2AC does not allege which specific products Plaintiff purchased, how many of each product she purchased, or when those products were purchased and/or consumed. Likewise, Plaintiff alleges generally that she saw and relied on all of the marketing phrases which she now claims are false and misleading but does not allege when or where she saw and relied upon those statements. *Id.* at ¶ 74. She also alleges she viewed CytoSport’s website and television advertisements “[i]n deciding to purchase” the products and relied on the representations contained therein, but provides no further detail. *Id.* at ¶ 76. And notwithstanding this Court’s prior finding that Plaintiff had not alleged a long-term advertising campaign, Plaintiff again alleges that she was exposed to and relied on “CytoSport’s extensive and long-term advertising campaign,” although she offers nothing additional to her allegations in 1AC and previously filed materials subject to judicial notice to support this claim. *Id.* at ¶ 77.

Despite its litany of claims, the 2AC again fails to provide the factual foundation necessary for Plaintiff to survive a motion to dismiss. While the 2AC has increased in length, it still lacks the facts that this Court previously found were necessary to state a claim.

III. ARGUMENT

A. Legal Standard

A motion to dismiss made under Federal Rule of Civil Procedure 12(b)(6) “tests the legal sufficiency of a claim.” *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001). Consequently, under Rule 8(a)(2), a motion to dismiss should be granted when a plaintiff fails to proffer “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is not plausible when a complaint’s allegations suggest only “the mere possibility of misconduct.” *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). While allegations of material fact are

1 assumed to be true, and viewed in the light most favorable to the plaintiff, the Court need not accept
 2 as true allegations that are conclusory, legal conclusions, unwarranted deductions of fact, or
 3 unreasonable inferences. *See id.*

4 When alleging a claim sounding in fraud, a plaintiff must plead the circumstances constituting
 5 fraud with particularity. Fed. R. Civ. P. 9(b); *see also Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097,
 6 1103 (9th Cir. 2003). “Averments of fraud must be accompanied by the who, what, when, where,
 7 and how of the misconduct charged.” *Vess*, 317 F.3d at 1106 (internal quotation marks omitted). A
 8 “plaintiff must set forth what is false or misleading about a statement, and why it is false.” *Id.*
 9 (internal quotation marks omitted). This is true as well for claims under the UCL, FAL, or CLRA
 10 that are “‘grounded in fraud’ or . . . ‘sound in fraud.’” *Kearns v. Ford Motor Co.*, 567 F.3d 1120,
 11 1125 (9th Cir. 2009) (quoting *Vess*, 317 F.3d at 1103-04); *see also Herrington v. Johnson & Johnson*
 12 *Consumer Co.*, No. C 09-1597 CW, 2010 WL 3448531, at *6-7 (N.D. Cal. Sept. 1, 2010).

13 **B. Plaintiff Has Failed To Plead An Actionable Misrepresentation Under The UCL, FAL,**
 14 **CLRA, Or Common Law**

15 To state a claim based on misrepresentation under the UCL, FAL, or CLRA, a statement must
 16 be likely to deceive a reasonable consumer. *See Williams v. Gerber Prod. Co.*, 552 F.3d 934, 938
 17 (9th Cir. 2008). To state a common law claim for fraud or negligent misrepresentation, a consumer
 18 must have justifiably relied on a representation that is false or subject to a misleading omission. *See*
 19 *Robinson Helicopter Co., Inc. v. Dana Corp.*, 34 Cal. 4th 979, 990 (2004); *Century Sur. Co. v.*
 20 *Crosby Ins., Inc.*, 124 Cal. App. 4th 116, 129 (2004).

21 While the reasonable consumer “may be unwary or trusting,” she is not the “least
 22 sophisticated consumer.” *Lavie v. Proctor & Gamble Co.*, 105 Cal. App. 4th, 496, 506-07 (2003).
 23 Nor does she lack minimal perseverance and common sense in investigating a product’s true nature.
 24 Reasonable consumers, for example, understand that “Crunchberries” are not an actual fruit, or that
 25 not all Danish pastry is made in Denmark. *See Sugawara v. Pepsico, Inc.*, No. 2:08-cv-1335, 2009
 26 WL 1439115, at *3 (E.D. Cal. May 21, 2009); *Lavie*, 105 Cal. App. 4th at 507. The likelihood of
 27 confusion is not to be evaluated by the odds that an advertising message might confuse someone,
 28 somewhere. *See Freeman v. Time, Inc.*, 68 F.3d 285, 289-90 (9th Cir 1995).

As in the 1AC, Plaintiff again fails to make “particularized allegations” that “set forth what is false or misleading” about CytoSport’s claims and “why [they are] false.” *Vess*, 317 F.3d at 1106; *see also Herrington*, 2010 WL 3448531, at *7 (plaintiffs did “not plead facts to suggest that the misrepresentations of which they complain were false” in support of their UCL, FAL, and CLRA claims); *Bardin v. Daimlerchrysler Corp.*, 136 Cal. App. 4th 1255, 1275 (2006) (deeming insufficient an allegation that “merely concludes the public would likely be deceived, without pleading any facts showing the basis for that conclusion”). Nor, with respect to Plaintiff’s CLRA claims, has she alleged any facts suggesting that CytoSport has represented that Muscle Milk® has characteristics or uses that it does not have, is of a particular standard when it is of another, or has advertised Muscle Milk® with an intent not to sell it as advertised. Although the 2AC contains conclusory allegations of supposedly false statements by CytoSport, Plaintiff has failed to amend the complaint to add the alleged facts the Court deemed necessary to render her claims sufficient.

1. The 14 Ounce RTD Bottle Contains No False Or Misleading Statement

Plaintiff attacks the following statements on the label of the 14 ounce RTD: (1) the claim “Healthy, Sustained Energy,” as well as the statements “25g PROTEIN” and “Protein Nutrition Shake” on the front of the bottle; (2) the statement “good carbohydrates” on the back of the bottle; and (3) the statement “healthy fats” also on the back of the bottle. 2AC at ¶¶ 20-25. Plaintiff also alleges that CytoSport’s website devoted to the 14 ounce RTD product falsely “claims that Muscle Milk® Ready-To-Drink (RTD) ‘promotes healthy sustained energy’ and that it provides ‘healthy fats’ and ‘good carbohydrates.’” *Id.* at ¶ 27. Finally, Plaintiff alleges that “CytoSport’s television advertisements feature the label from the 14 ounce size of the [RTD], and republish the false and misleading claim ‘Healthy, Sustained Energy’ in connection with the statements ‘Protein Nutrition Shake,’ ‘25g PROTEIN,’ and ‘It’s powerful protein.’” *Id.* at ¶ 30. None of these are actionable as false or misleading statements. And with the exception of Plaintiff’s challenge to the term “good carbohydrates,” the Court has already addressed the alleged misrepresentations, and rejected all but the “healthy fats” allegation. *See* Dkt. 34 at 12-14.

a. “Good Carbohydrates”

Plaintiff challenges CytoSport’s use of the phrase “good carbohydrates” on the back of the label of the 14 ounce RTD and on the CytoSport website for the 14 ounce RTD. 2AC at ¶¶ 22-23, 25, 27-28. Plaintiff asserts that the inclusion of the ingredients fructose (a/k/a “fruit sugar”), acesulfame potassium, and sucralose in the 14 ounce RTD product render the claim “good carbohydrates” misleading—implying that the ingredients are “bad carbohydrates.” Plaintiff, however, does not identify what a “good carbohydrate” is or why the use of those ingredients should preclude CytoSport from using the term “good carbohydrates.” Both acesulfame potassium and sucralose have been approved for use in food by the FDA. 21 C.F.R. §§ 172.800, 172.831. And Plaintiff does not specify the amount of fructose, acesulfame potassium, or sucralose that would trigger the adverse effects Plaintiff opines they cause or that such amounts are present in Muscle Milk®. This is particularly relevant where, as here, the 14 ounce RTD product contains a total of 12 grams of carbohydrates, only 3 grams of which are “sugars” of any type.³ By comparison, an apple has more than six times the sugar of a 14 ounce bottle of Muscle Milk RTD—19 grams in a medium apple compared to 3 grams in the 14 ounce RTD product. *See* <http://nutritiondata.self.com/facts/fruits-and-fruit-juices/1809/2> (last visited May 2, 2012). This illustrates that there is no common understanding of what a “bad” or “good” carbohydrate is and the 2AC fails to allege facts to the contrary. *See Lavie*, 105 Cal. App. 4th, 496, 508 (“‘Likely to deceive’ implies more than a mere possibility that [an] advertisement might conceivably be misunderstood by some few consumers viewing it in an unreasonable manner. Rather, the phrase indicates that the ad is

³ Although the 2AC contains some images of the front and the back of the 14 ounce RTD bottle, it strategically omits images of the nutritional information. The nutritional information, however, can be found at <http://www.cytosport.com/products/muscle-milk/muscle-milk-ready-to-drink>. The 2AC specifically references and relies upon this portion of CytoSport’s website. *See* 2AC ¶¶ 26-29, 68. This Court may accordingly rely on that portion of the website in making its ruling. *See Parrino v. FHP, Inc.*, 146 F.3d 699, 706 (9th Cir. 1998) (superseded by statute on other grounds) (“[A] district court ruling on a motion to dismiss may consider a document the authenticity of which is not contested, and upon which the plaintiff’s complaint necessarily relies.”) The nutrition label for the 14 ounce RTD product, as displayed on CytoSport’s website, is attached as Exhibit B to the Nierlich Decl.

1 such that it is probable that a significant portion of the general consuming public or of targeted
 2 consumers, acting reasonably in the circumstances, could be misled.”).

3 **b. “Healthy, Sustained Energy”**

4 This Court has already rejected the contention, with respect to the 17 ounce RTD, that
 5 “Healthy, Sustained Energy” is false or misleading because the “term ‘healthy’ is difficult to define”
 6 and Plaintiff supplied no objective standard to establish what makes a given product healthy or
 7 unhealthy. Dkt. 34 at 13:24-14:10. Apparently seeking reconsideration of this Court’s ruling,
 8 Plaintiff now turns her attention to the same language on a different-sized bottle—the 14 ounce RTD.
 9 This is even though Plaintiff acknowledges that she did not begin to use any Muscle Milk® products
 10 until February 2011 (2AC at ¶ 73), and she also acknowledges that the label for the 14 ounce RTD
 11 was changed in February 2011 to *remove* the phrase “Healthy, Sustained Energy.” *Id.* at ¶ 22.

12 In any event, the 2AC does not explain how the phrase “Healthy, Sustained Energy,” as
 13 depicted on the 14 ounce RTD bottle, is any different from the very same phrase on the 17 ounce
 14 bottle, which this Court already ruled is not misleading, absent some objective standard against which
 15 a product’s ratio of protein to fat must be measured. Dkt. 34 at 14:5-10.⁴ Indeed, a full 14 ounce
 16 bottle of Muscle Milk® RTD contains 25 grams of protein (50% of the recommended daily amount)
 17 but only contains 9 grams of fat (14% of the recommended daily amount)—approximately 2.8 grams
 18 of protein per gram of fat. *See* Nierlich Decl., Ex. B. Plaintiff has not alleged that this ratio of
 19 protein to fat somehow renders the product incapable of providing “healthy, sustained energy.”
 20 Recognizing as much, Plaintiff now presses the unsupported contention that protein is bad for you
 21 because some people already consume enough protein. 2AC at ¶ 4. But the 2AC contains no
 22 allegations that the protein in Muscle Milk® is harmful or that consuming Muscle Milk® will
 23 somehow result in the consumption of dangerous levels of protein. And Plaintiff admits that the front
 24 of the label readily identifies the amount of protein in the product, which allows consumers to readily
 25 determine whether they desire the protein provided in Muscle Milk®. *See* 2AC at ¶ 22. Plaintiff has
 26

27 ⁴ Plaintiff may intend to rely solely on her allegation that “‘Healthy, Sustained Energy’ in
 28 connection with the statements ‘Protein Nutrition Shake’ and ‘25g PROTEIN’” is misleading
 because it violates federal food labeling regulations. This argument is faulty and is discussed
 below at section III.C, *infra*.

thus failed to allege that the 14 ounce RTD's protein content somehow makes the statement "Healthy, Sustained Energy" misleading or deceptive. *See Vess*, 317 F.3d at 1106.

c. "25g PROTEIN" And "Protein Nutrition Shake"

Neither the phrase "25g PROTEIN" nor "Protein Nutritional Shake" constitutes a false or misleading statement. Plaintiff does not contest that the 14 ounce RTD contains 25 grams of protein. Likewise, "Protein Nutrition Shake" is the type of product being sold and the 2AC does not contain any allegation that this description of the 14 ounce RTD is false or misleading.

d. "Healthy Fats"

Plaintiff again challenges the use of "healthy fats" on the back of the label of the 14 ounce RTD bottle—the only claim that the Court found actionable in the 1AC. 2AC at ¶¶ 22-24. CytoSport recognizes that this Court has rejected its argument that any alleged misrepresentation was cured by the nutritional information included on the bottle's packaging. Nonetheless, CytoSport respectfully maintains that the labeling on the 14 ounce RTD is different in nature from that at issue in *Williams v. Gerber*. Dkt. 14 at 7-8; Dkt. 34 at 13:10-23. "Healthy fats" appears in small font as part of a long description (totaling 64 words) on the back of the 14 ounce RTD—unlike the *Gerber* packaging which contained a number of affirmative misrepresentations on the front of the packaging (pictures of fruits and the phrase "with real fruit juice").⁵ *See Williams*, 552 F.3d at 939; Nierlich Decl. at Ex. C.

e. Website And Television Statements Regarding 14 Ounce RTD

Plaintiff alleges that certain statements on the CytoSport website "compound" the misrepresentations on the 14 ounce RTD's label. 2AC at ¶ 26. Namely, Plaintiff attacks the statements that Muscle Milk® RTD "'promotes healthy sustained energy,' and that it provides 'healthy fats' and 'good carbohydrates.'" *Id.* at ¶ 28. These are the same statements addressed in detail above, and they are not actionable. Plaintiff also alleges that the statement suggesting when consumers should use Muscle Milk®, found on CytoSport's website, is a misrepresentation, but does

⁵ Although Plaintiff asserts a cause of action based on the alleged use of the term "Functional Fats," the 2AC does not contain any detail about where such terms exist on any CytoSport product, website, or advertisement. 2AC at ¶¶ 100, 133, 139. Nor does the 2AC specify why Plaintiff alleges that the phrase "functional fat" is misleading or deceptive. This challenge is inadequately plead and does not state a claim.

not allege any additional facts to suggest why this is so. 2AC at ¶ 29. Nor is there any explanation of how these statements are used in Internet or television advertising.

2. The Label For Muscle Milk® Bars Makes No False Or Misleading Statement

With respect to the Muscle Milk® Bars, Plaintiff alleges: (1) the statement “25g PROTEIN for healthy, sustained energy” is false or misleading because of the Bars’ fat content; (2) that the Bars are unhealthy because they contain palm oil; and (3) the nutritional information for the Vanilla Toffee Crunch Bar is inaccurate. 2AC at ¶¶ 32-39. Plaintiff further alleges that the CytoSport website states, with respect to Muscle Milk® Bars, that “‘there’s no question [you’re] getting a nutritious snack,’ and that ‘Muscle Milk Bars are loaded with 25 grams of high-quality muscle source protein,’ and ‘Muscle Milk Bars deliver . . . healthy sustained energy.’” 2AC at ¶¶ 41-42. As with the 14 ounce RTD, none of these statements are actionable. With the exception of the specific allegations related to the Vanilla Toffee Crunch Bar, these are repetitions of claims that this Court has rejected.

a. “25g PROTEIN for Healthy, Sustained Energy”

The Court explicitly rejected Plaintiff’s assertion that the statement “25g PROTEIN for healthy, sustained energy” on the Muscle Milk® Bar labels was misleading. Dkt. 34 at 14:11-14 (“Plaintiff also challenges the ‘Healthy, Sustained Energy’ language on the label for the Bars. However, that label reads, ‘25g PROTEIN FOR HEALTHY, SUSTAINED ENERGY.’ Plaintiff does not claim that the Bars do not contain twenty-five grams of protein.”). The 2AC contains no new allegation that warrants reconsideration of this ruling. Plaintiff does not now allege that the Muscle Milk® Bars do not contain 25 grams of protein. Instead, Plaintiff relies on her new and unsupported contention that the protein in Muscle Milk® is somehow bad for you. 2AC at ¶¶ 4, 34. But, again, the 2AC provides no basis to draw the conclusion that Muscle Milk® Bars are unhealthy because of their protein content, as it fails to specify what is supposedly “too much” protein or what “detrimental effects on health” would ensue upon consumption of “too much” protein. 2AC at ¶ 4. Moreover, the 2AC cannot allege that the Muscle Milk® bar itself provides “too much” protein, as it provides about half of the recommended daily protein intake. Whatever other dietary choices an individual may make with respect to protein cannot somehow transform the protein in Muscle Milk® into “too much” protein for that person (even if Plaintiff could define what “too much” protein is).

The 2AC also rehashes the previously-rejected argument that “Healthy, Sustained Energy” is misleading because the Bars are generally unhealthy (in Plaintiff’s view) due to their fat content. Again, the phrase that Plaintiff attacks is “25g PROTEIN for healthy, sustained energy,” and, again, Plaintiff does not credibly allege that protein is unhealthy. Plaintiff also argues that a Muscle Milk® Bar is “less healthy” than a Snickers® Bar. 2AC at ¶ 34. But as the Court previously found, simply noting the similarities between the fat, sugar, and calorie content of two items is not helpful in determining whether calling an item “healthy” is misleading. Dkt. 34 at 14:2-8 (“While Plaintiff alleges that Muscle Milk® RTD contains unspecified amounts of saturated fat that are equal to or exceed that in certain Krispy Kreme doughnuts, this analogy is not helpful. Plaintiff does not explain how much protein, vitamins and minerals are in such a doughnut or posit an objectively healthy ratio of protein to fat.”).⁶ What is more, a Muscle Milk® Bar is 24% larger than a Snickers® Bar, making Plaintiff’s comparison of the nutritional contents of the two products even less helpful. 2AC at ¶ 34 (noting that a Muscle Milk® Bar is 2.57 ounces and a Snickers® Bar is 2.07 ounces).

b. Palm Oil

The 2AC repeats Plaintiff’s allegations from the 1AC regarding fractionated palm kernel oil and partially hydrogenated palm oil. Specifically, Plaintiff alleges both that the presence of palm oil makes the statement “25g PROTEIN for healthy, sustained energy” false or misleading because palm oil is unhealthy, and that the presence of partially hydrogenated palm oil makes the statement “0g Trans Fat” false or misleading. 2AC at ¶¶ 34, 37-39. This Court already rejected Plaintiff’s claims based on fractionated palm kernel oil and partially hydrogenated palm oil, however, because the 1AC did not identify either as trans fats. Dkt. 34 at 14:15-20. The 2AC now alleges that partially hydrogenated palm oil is a trans fat and that Muscle Milk® Bars contain it. 2AC at ¶¶ 6-7. But Plaintiff does not allege how much partially hydrogenated palm oil is in Muscle Milk® Bars, and specifically does not allege that the Bars contain more than 0.5 grams of trans fat per serving. This is a crucial failure of pleading, as federal regulations provide that if a product contains less than 0.5 grams of trans fat per serving, the amount of trans fat “shall be expressed as zero.” 21 C.F.R.

⁶ A typical Muscle Milk® bar contains 25 grams of protein, and only 11 grams of fat, or approximately 2.27 grams of protein per gram of fat. 2AC ¶¶ 34, 35, 71.

§ 101.9(c)(2)(ii). Thus, Plaintiff does not allege facts sufficient to show that the Muscle Milk® Bars should not be labeled as “0g Trans Fat.” Moreover, the presence of palm oil (whether or not a trans fat) has no bearing on whether the statement “25g PROTEIN for healthy, sustained energy” is deceptive because that statement says nothing about fats, only protein.

c. “Healthy, Sustained Energy” Advertisement On CytoSport’s Website

Plaintiff also challenges various statements on the Muscle Milk® website devoted to the Bars involving the phrase “healthy, sustained energy” and similar statements. *See* 2AC ¶¶ 41-42. As stated above, this Court has already ruled that the statement “Healthy, Sustained Energy” is not sufficient to state a claim for misrepresentation. Dkt. 34 at 13:24-14:10.

C. Plaintiff Cannot Rely On Federal Food Labeling Regulations To Save Her Claims

Since Plaintiff cannot identify with any specificity what is false or misleading about CytoSport’s labels, she now argues that the various statements contained on the 14 ounce RTD and Bar products are “misleading because they are misbranded” under the Federal Food Drug and Cosmetic Act (“FDCA”) and the FDA’s regulations promulgated thereunder, which have been incorporated into the California Health and Safety Code through the Sherman Food, Drug, and Cosmetic Law. 2AC at ¶¶ 43, 57. Specifically, Plaintiff challenges the following statements as unauthorized nutrient content claims under the FDCA and FDA regulations: (1) The “‘Healthy, Sustained Energy’ claim in connection with the statements ‘Protein Nutrition Shake’ and ‘25g PROTEIN’” on the 14 ounce RTD’s label; (2) the “‘25g PROTEIN for Healthy, Sustained Energy’ claim in connection with the claim ‘0g Trans Fat’” on the Muscle Milk® Bar label; and (3) the phrase “0g Trans Fat” also on the Muscle Milk® Bar label. *Id.* at ¶¶ 43-71.

Plaintiff’s new embrace of federal food labeling regulations promulgated, interpreted, and enforced by the FDA cannot save her claims. *First*, despite Plaintiff’s conclusory allegations to the contrary, an alleged technical violation of FDA regulations does not automatically render an advertising statement false or misleading. Thus, the allegation that a product’s label may not be compliant with any one of the numerous FDA regulations is irrelevant to the claims at issue, because regulatory non-compliance does not necessarily make a label deceptive. *Second*, CytoSport has not violated the relevant FDA regulations. *Third*, if any question remains as to whether CytoSport has

committed a technical violation, this is a question best resolved by the FDA. *Fourth*, Plaintiff should not be allowed to add these new allegations because she previously abandoned any reliance on FDA regulations.

1. Plaintiff's Allegations Concerning Technical Violations Of FDA Regulations Cannot Support Any Of Her Misrepresentation Claims

Plaintiff alleges that “CytoSport’s labels for the Products are misleading . . . *because* they are misbranded” (2AC at ¶ 57), but she misapplies the plain language and structure of the FDCA. Food may be misbranded *because* its labeling is misleading, but food labeling is not necessarily misleading *because* the food is misbranded. Section 343 of Title 21 of the United States Code governs purportedly misbranded food. Under section 343, food can be misbranded if certain things about it, like its label or container, are “misleading.” *See, e.g.*, 21 U.S.C. §§ 343(a)(1) (food misbranded if “its labeling is false or misleading in any particular”), 343(d) (food misbranded if container misleading). But food can also be misbranded even when its labeling is not misleading. *See, e.g., id.* at § 343(e) (deeming food misbranded if its packaging omits the manufacturer’s name and place of business, and quantity of food in package). Accordingly, under the FDCA, food labeling is not automatically “misleading” even if the food is misbranded.

Likewise, the FDA’s regulations governing implied nutrient content claims recognize that a labeling violation can occur without making a misleading statement. Sections 343(r)(1)(A) and (r)(2)(A)(i) of Title 21 of the United States Code require that claims on a food product’s label that “characterize[] the level of [certain] nutrient[s]” be made only if, *inter alia*, they comply with FDA regulations. 21 U.S.C. §§ 343(r)(1)(A), 343(r)(2)(A)(i). Under the applicable FDA regulations, nutrient content claims are those that “expressly or implicitly characterize[] the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.36.”⁷ 21 C.F.R. § 101.13(a). An “expressed nutrient content claim” is “any direct statement about the level (or range) of a nutrient in the food, *e.g.*, ‘low sodium’ or ‘contains 100 calories.’” *Id.* at § 101.13(b)(1). An “implied nutrient content claim” is any claim that “describes the food or an ingredient therein in a manner that

⁷ These two sections govern the particular information required to be disclosed on food or supplement nutrition labels.

1 suggests that a nutrient is absent or present in a certain amount” or “[s]uggests that the food, because
 2 of its nutrient content, may be useful in maintaining healthy dietary practices and is made in
 3 association with an explicit claim or statement about a nutrient (*e.g.*, ‘healthy, contains 3 grams (g) of
 4 fat’).” *Id.* at § 101.13(b)(2).

5 With respect to implied nutrient content claims concerning a product’s healthiness, according
 6 to section 101.65, which is part of subpart D of the FDA’s regulations, a statement is an implied
 7 nutrient content claim when it: “(i) [s]uggests that a food because of its nutrient content may help
 8 consumers maintain healthy dietary practices; and (ii) [is] made in connection with an explicit or
 9 implicit claim or statement about a nutrient (*e.g.*, ‘healthy, contains 3 grams of fat’).” 21 C.F.R.
 10 § 101.65(d)(1). For an advertiser to use the word “healthy” and its cognates in an implied nutrient
 11 content claim, the advertised product must meet certain requirements regarding the levels of fat,
 12 saturated fat, cholesterol, sodium, and other nutrients. *Id.* at § 101.65(d)(2).

13 Critically, section 101.13 provides that a food label:

14 may contain a statement about the amount or percentage of a nutrient if: (1) The use of
 15 the statement on the food implicitly characterizes the level of the nutrient in the food
 16 and is consistent with a definition for a claim, as provided in *subpart D* of this part, for
 17 the nutrient that the label addresses. Such a claim might be, “less than 3 g of fat per
 18 serving;” . . . or (3) The statement does not in any way implicitly characterize the level
 19 of the nutrient in the food and it is not false or misleading in any respect[.]”

20 21 C.F.R. § 101.13(i) (emphases added). That is, a food label can include a nutrient content claim for
 21 at least one of two independent reasons: (1) it complies with subpart D, including section 101.65, or
 22 (2) “it is not false or misleading.” As with the FDCA itself, the FDA’s regulations governing nutrient
 23 content claims recognize that a label can violate particular technical requirements (*e.g.*, section
 24 101.65 as part of subpart D) and still not be misleading.

25 Plaintiff alleges that the FDA’s “[n]utrient content regulations are designed to protect
 26 consumers from being misled by claims that a product is a healthy choice even though it actually has
 27 unhealthy levels of fat and saturated fat, because it is purportedly low in trans fat, or contains certain
 28 ‘healthy’ ingredients.” *Id.* at ¶ 60; *see also id.* at ¶ 48. But this is a mere legal conclusion that this
 Court is not bound to accept as true. *See Iqbal*, 556 U.S. at 679. In any event, courts recognize that
 even if some statement on a label somehow violates a technical FDA regulation, this does not make

that statement false or misleading. For example, the Third Circuit has concluded that a plaintiff could not claim that a defendant's cough syrup label was "misleading to the consuming public" even though the plaintiff submitted evidence that the disputed label may have violated FDA regulations. *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3d. Cir. 1990).⁸ Likewise, in *Mason v. Coca-Cola Co.*, 774 F. Supp. 2d 699 (D.N.J. 2011), a putative class action was filed within weeks of, and based entirely upon, an FDA warning letter claiming technical noncompliance with federal labeling requirements. *See* Third Am. Compl. ¶¶ 1-3, 11-20, *Mason v. Coca-Cola Co.*, No. 09-220 (D.N.J. July 12, 2010) (Dkt. No. 35). The FDA warning letter in *Mason* asserted that a product label did not comply with FDA requirements because the word "plus" in the product name ("Diet Coke Plus") characterized the product's relative nutrient content without specifying the basis for the comparison, and it improperly portrayed a snack food as "fortified." *See id.*, Ex. A. "At its core," the district court there explained, "the complaint is an attempt to capitalize on an apparent and somewhat arcane violation of FDA food labeling regulations. But not every regulatory violation amounts to an act of consumer fraud. It is simply not plausible that consumers would be aware of FDA regulations regarding 'nutrient content.'" *Mason*, 774 F. Supp. 2d at 705 n.4.

The same logic applies here. As this Court and others have recognized, the word "healthy" is "difficult to define." Dkt. 34 at 13:26; *see also Yumul v. Smart Balance, Inc.*, 733 F. Supp. 2d 1117, 1129-30 (C.D. Cal. 2010). There is no reason to believe that the reasonable consumer defines the term "healthy" according to arcane FDA regulations. Nor is it the fact that a failure to include the words "[s]ee nutrition information for saturated fat content" when a label includes the words "0g Trans Fat" somehow prevents consumers from knowing the amount of other nutrients in a product. *See Pearson*, 164 F.3d at 655; 2AC at ¶¶ 63-64. As such, Plaintiff's allegations concerning supposed

⁸ While the 2AC cites a "Dear Industry" letter from the FDA for the proposition that unauthorized nutrient content claims are inherently misleading (*see* 2AC at ¶ 61), this position has previously been rejected. In *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), the D.C. Circuit considered the FDA's argument that "health claims" made on nutritional supplements that had not received FDA approval as being supported by "significant scientific agreement" were "inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment *at the point of sale*." *Id.* at 655. This was not tenable: "It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous." *Id.*

1 technical violations of FDA regulations cannot support her claims of misrepresentation; at most, such
 2 allegations might support her claim that CytoSport violated the UCL by acting unlawfully.

3 **2. CytoSport Has Not Made Improper Nutrient Content Claims**

4 In any event, the challenged statements are not unauthorized nutrient content claims. As
 5 described above, the FDA has promulgated specific regulations governing when “healthy” is used as
 6 part of a nutrient content claim: when a label includes a statement that “(i) [s]uggests that a food
 7 because of its nutrient content may help consumers maintain healthy dietary practices; and (ii) [is]
 8 made in connection with an explicit or implicit claim or statement about a nutrient (*e.g.*, ‘healthy,
 9 contains 3 grams of fat’).” 21 C.F.R. § 101.65(d)(1). In promulgating its regulations concerning the
 10 use of the word “healthy,” the FDA acknowledged that the word is “difficult to define” and that not
 11 all uses of the word “healthy” are nutrient content claims. 58 Fed. Reg. 2302, 2375. Rather, when
 12 the term “healthy” is not an implied nutrient content claim, it is governed by section 21 U.S.C.
 13 § 343(a), which, as discussed above, concerns “false or misleading” labeling. *See* 58 Fed. Reg. at
 14 2375 (“[W]hen a term such as ‘healthy,’ ‘wholesome,’ and ‘nutritious’ appears on a food label in a
 15 context that does not render it an implied nutrient content claim, it is not subject to the requirements
 16 of section 403(r) of the act. Under such conditions, the use of the term is subject to section 403(a) of
 17 the act, and FDA will determine whether it is misleading on a case-by-case basis.”).

18 In an attempt to create a nutrient content claim where one does not exist, Plaintiff tries to
 19 stitch together the separate phrases “Healthy, Sustained Energy,” “Protein Nutrition Shake,” and “25g
 20 PROTEIN” that appear in different parts of the 14 ounce RTD label into a single alleged advertising
 21 “claim ‘Healthy, Sustained Energy’ *in connection with* the statements ‘Protein Nutrition Shake’ and
 22 25g PROTEIN.” *See, e.g.*, 2AC at ¶¶ 20, 68 (emphasis added); *see also* Nierlich Decl. at Ex. A.
 23 This reading of the label of the 14 ounce RTD strains the meaning of “in connection with” in the
 24 FDA’s regulations past its breaking point. As those regulations make clear by their examples, the
 25 term “in connection with” requires that the various components of the alleged implied nutrient
 26 content claim appear in the same sentence or phrase, “connect[ing]” the word “healthy” directly to
 27
 28

the nutrient content claim. *See* 21 C.F.R. § 101.65(d)(1) (providing example of “healthy, contains 3 grams of fat”); *id.* at § 101.13(b)(2) (same).⁹

This is plainly not the case with the 14 ounce RTD label. The terms “25g PROTEIN” and “Protein Nutrition Shake” are statements made separately from the term “Healthy, Sustained Energy.” *See* 2AC at ¶ 22. The presentation of the words “Healthy, Sustained Energy” is visually distinct from the portions of the label bearing the phrases “Protein Nutrition Shake” and “25g PROTEIN.” “Protein Nutrition Shake” is separated from “Healthy, Sustained Energy” by a line of text stating “Contains No Milk.” “25g PROTEIN” is itself separated from both “Healthy, Sustained Energy” and “Protein Nutrition Shake” by a large swirling image, and the borders of a self-contained text box. There simply is no “connect[ion]” between these disparate phrases under any logical understanding of the term. Plaintiff may not cobble together these distinct statements to create a single purported advertising statement that she contends violates FDA regulations.¹⁰

Plaintiff also attacks the “claim ‘25g PROTEIN for Healthy, Sustained Energy’ in connection with the claim ‘0g Trans Fat’” as an improper implied nutrient content claim on the label of Muscle Milk® Bars. 2AC at ¶ 70. But the word “healthy” in the statement “25g PROTEIN for Healthy, Sustained Energy” modifies the word “energy,” *i.e.*, the 25 grams of protein in the product provide a healthy source of energy. As such, this “claim” is not an implied nutrient content claim because it does not “suggest that a food because of its nutrient content may help consumers *maintain healthy dietary practices*,” 21 C.F.R. § 101.65(d)(1) (emphasis added), but instead makes a limited statement about the nature of the energy provided by the Bar.¹¹

⁹ A construction of “in connection with” that permits the random grafting together of disparate and otherwise lawful statements on a label to create an allegedly unauthorized nutrient content claim would also be susceptible to a constitutional challenge as both void for vagueness and violative of an advertiser’s First Amendment rights. *See, e.g., Int’l Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67, 69 (2d Cir. 1996).

¹⁰ Plaintiff has included a smaller image of the 14 ounce RTD bottle in the 2AC. *See* 2AC at ¶ 22. For ease of reference, CytoSport has provided a larger image of the 14 ounce bottle as Exhibit C to the Nierlich Decl.

¹¹ Plaintiff’s inclusion of the “0g Trans Fat” statement with “25g PROTEIN for healthy, sustained energy” suggests that Plaintiff does not believe the statement “25g PROTEIN for healthy, sustained energy” constitutes a nutrient content claim on its own—which conflicts with her position with respect to the 14 ounce RTD that “Healthy, Sustained Energy” read in connection

3. The Primary Jurisdiction Doctrine Requires Dismissal Or A Stay

Given Plaintiff's new-found reliance on the FDCA and FDA regulations, a stay or dismissal in deference to the FDA's primary jurisdiction is also warranted. The primary jurisdiction doctrine "requires judicial abstention in cases where protection of the integrity of a regulatory scheme dictates preliminary resort to the agency which administers the scheme." *United States v. Phila. Nat'l Bank*, 374 U.S. 321, 353 (1963). While there is "no fixed formula," the Ninth Circuit generally looks at four factors to determine if an agency has primary jurisdiction over a matter: if "there is (1) [a] need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1115 (9th Cir. 2008) (internal quotation marks omitted).

Here, Plaintiff bases her claims on misbranding under the FDCA and the FDA regulations. *See, e.g.*, 2AC at ¶¶ 43-71, 74. Indeed, she recognizes that the FDA's regulations were wholly incorporated into California law, and Plaintiff includes near carbon copies of allegations from the FDA's warning letter (which has not yet been resolved) in the 2AC. *Compare* 2AC at ¶¶ 43, 46, 48-56, 62-71 (citing 21 U.S.C. § 343 and 21 C.F.R. § 101.13) *with* Nierlich Decl., Ex. A.

The propriety of the statements challenged in the 2AC is an issue explicitly placed by Congress within the FDA's exclusive jurisdiction. *See, e.g.*, 21 U.S.C. § 337(a); 21 C.F.R. § 10.25(b); *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 349 n.5 (2001); *see also* *Aaronson v. Vital Pharm., Inc.*, 2010 WL 625337, at *2 (S.D. Cal. Feb. 17, 2010) (the FDA "more than the average consumer, knows how to weigh conflicting studies and determine the most accurate and up-to-date information[]"). Moreover, the assessment of the statements challenged here, and whether they violated FDA regulations, is still before the FDA, as CytoSport has not received a notification from the FDA closing its inquiry. *See* Nierlich Decl. at Exs. A, D, & E. As there is already an inquiry by the FDA into the same labeling Plaintiff challenges in the instant suit, a foray

with "Protein Nutrition Shake" and "25g PROTEIN" does create a nutrient content claim. This conflict undermines Plaintiff's argument and helps to illustrate why the FDA, and not private parties, should interpret and enforce FDA regulations, as is discussed in greater detail in the following section.

into these issues by this Court in a private class action creates a high risk of inconsistent rulings. *See United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 64 (1956) (with the primary jurisdiction doctrine, “[u]niformity and consistency in the regulation of business entrusted to a particular agency are secured”) (internal quotation marks omitted); *Physicians Comm. for Responsible Medicine v. General Mills, Inc.*, No. 1:05cv958, 2006 WL 3487651, at *6 (E.D. Va. Nov. 30, 2006). The regulatory and scientific issues at stake here “stray[] too close to the exclusive enforcement domain of the FDA.” *Summit Tech., Inc. v. High-Line Med. Instruments Co.*, 933 F. Supp. 918, 933 (C.D. Cal. 1996) (citation omitted). Accordingly, the action should be dismissed or stayed in its entirety.¹²

4. Plaintiff Should Not Be Allowed To Add Allegations That Rely On The FDCA And Its Regulations

Finally, Plaintiff should not even be able to add her new allegations concerning violations of FDA regulations in light of both this Court’s dismissal order and the doctrine of equitable estoppel.

Opposing CytoSport’s motion to dismiss the 1AC, Plaintiff maintained that the claims therein were “not predicated on FDA regulations” and “[we]re brought under the CLRA, UCL, FAL, and the common law.” Plaintiff’s Opposition to Defendant CytoSport, Inc.’s Motion to Dismiss First

¹² Further, Plaintiff’s revised claims based on CytoSport’s alleged misbranding are nothing more than claims for alleged regulatory violations under the FDCA and should be dismissed with prejudice, as was the result in *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, No. MDL 08-1934, 2009 WL 1703285, at *5 (C.D. Cal. Jun. 17, 2009). Plaintiff’s reliance on California’s Sherman Food, Drug, and Cosmetic Law cannot overcome the federal bar on private enforcement. Although *In re Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 1082 (2008), determined that a complaint was “independent” of the FDCA because it invoked the Sherman Law and because the defendant allegedly violated parallel and identical state and federal disclosure laws, that court did not identify any basis for inferring a federal private damages remedy based on violations of either the FDCA or state statutes that merely incorporate the FDCA by reference. Moreover, permitting private enforcement of FDA regulations—even when incorporated into state law—interferes with and obstructs the FDA’s interest in nationally-uniform food labeling regulations. *See* 21 U.S.C. § 337(a), (b)(2); *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 98, 103 (1992); *see also e.g., Fraker v. KFC Corp.*, No. 06-cv-1284-JM (WMC), 2007 WL 1296571, at *4 (S.D. Cal. Apr. 30, 2007) (“[T]he FDCA presents a comprehensive regulatory scheme of branding and labeling of food products. To overlay the state law tort system over the FDCA would significantly increase the burdens on the FDA to ensure uniform enforcement of its administrative duties.”). Not only do section 337 and principles of preemption preclude this result, but a rule allowing various states to make contradictory interpretations of the FDA’s national labeling regulations would impermissibly burden interstate commerce. *See, e.g., Bibb v. Navajo Freight Lines, Inc.*, 359 U.S. 520, 529-30 (1959).

1 Amended Complaint, or in the Alternative, to Stay all Claims, Dkt. 26 at 2:16, 22:17. The Court
 2 agreed with Plaintiff, concluding that a stay or dismissal under the primary jurisdiction doctrine was
 3 not appropriate because “Plaintiff’s complaint is not based on the FDA’s warning that the product
 4 labels violate its regulations” but was instead to be evaluated under the “reasonable consumer test.”
 5 Dkt. 34 at 26:27-27:1. Plaintiff was granted leave to amend, but only if she could “do so without
 6 contradicting the allegations in her original complaint.” *Id.* at 27:13-14. By adding her new
 7 allegations based on FDA labeling regulations, Plaintiff has plainly contradicted herself. Where she
 8 once disavowed any reliance on those regulations, she now embraces them. Plaintiff could have
 9 relied on FDA regulations and strategically chose not to do so.

10 The doctrine of equitable estoppel also prevents Plaintiff from making new allegations based
 11 on FDA regulations. In considering whether to apply equitable estoppel, a court is to consider: “(1)
 12 whether a party’s later position is ‘clearly inconsistent’ with its original position; (2) whether the
 13 party has successfully persuaded the court of the earlier position; and (3) whether allowing the
 14 inconsistent position would allow the party to ‘derive an unfair advantage or impose an unfair
 15 detriment on the opposing party.’” *United States v. Ibrahim*, 522 F.3d 1003, 1009 (9th Cir. 2008)
 16 (citing *New Hampshire v. Maine*, 532 U.S. 742, 750-51 (2001)).

17 All three factors are satisfied here. Plaintiff’s new reliance on the FDA regulations is
 18 inconsistent with her prior position that her claims were based only on the UCL, FAL, CLRA, and
 19 common law. This Court also relied on Plaintiff’s position in its Order. *See* Dkt. 34 at 26:27-27:1.
 20 This has benefited Plaintiff much to CytoSport’s disadvantage, namely because, for roughly four
 21 months, Plaintiff has been able to obtain discovery from CytoSport in this matter and to develop the
 22 alternate strategy embodied in the 2AC. Had this matter been stayed or dismissed initially, Plaintiff
 23 would have obtained no such advantage. She should not be allowed the free pass of a new complaint
 24 based on a theory she once rejected.

25 **D. Plaintiff Has Not Adequately Alleged Reliance On The New Advertising Statements**

26 To claim standing under the UCL, FAL, and CLRA, a plaintiff “proceeding on a claim of
 27 misrepresentation as the basis of his or her . . . action must demonstrate actual reliance on the
 28 allegedly deceptive or misleading statements, in accordance with well-settled principles regarding the

element of reliance in ordinary fraud actions.” *In re Tobacco II Cases*, 46 Cal. 4th 298, 306 (2009); *see also Meyer v. Sprint Spectrum, L.P.*, 45 Cal. 4th 634, 641 (2009). Similarly, to state a claim for fraud at common law, the alleged victim must have incurred damage *as a result of* the fraudulent deception. *In re Tobacco II*, 46 Cal. 4th at 312. In federal court, causation and reliance must be pleaded with particularity pursuant to Rule 9(b). *See Herrington*, 2010 WL 3448531, at *8 (*Tobacco II* “does not stand for, nor could it, a general relaxation of the pleading requirements under Rule 9(b)”); *In re Actimmune Marketing Litig.*, 2009 WL 3740648, at *8 (N.D. Cal. Nov. 6, 2009).

Plaintiff claims to have relied on a host of new advertising statements that were not alleged in the 1AC. Indeed, she seems to have relied on nearly everything on the labels for Muscle Milk® products (and similar statements on the Internet and television) *except* the products’ nutrition labels. In its Order, this Court granted Plaintiff leave to amend the 1AC only insofar as she could “truthfully do so.” Dkt. 34 at 27:13. Plaintiff cannot credibly have relied on the allegedly false or misleading statement on the 14 ounce RTD “‘Healthy, Sustained Energy’ in connection with the statements ‘Protein Nutrition Shake’ and ‘25g PROTEIN.’” 2AC ¶ 20. The 1AC said ***absolutely nothing*** about the words “healthy, sustained energy” on the label of the 14 ounce RTD. The only allegations about alleged false or misleading statements on that product label concerned the terms “healthy fats,” “good carbohydrates,” and the statement that Muscle Milk® RTD could help “reach your true potential.” 1AC at ¶ 18. Yet, Plaintiff now alleges that the statement “‘Healthy, Sustained Energy’ in connection with the statements ‘Protein Nutrition Shake’ and ‘25g PROTEIN.’” was “material” to her.¹³ 2AC at ¶ 74. It is not plausible (and strains credulity) to claim that something that was “material” to her purchasing decision was not important enough to actually allege in the 1AC.¹⁴ *See Twombly*, 550 U.S. at 570.

¹³ As discussed above, Plaintiff’s allegation that “healthy, sustained energy” should be read “in connection with the statements ‘Protein Nutrition Shake’ and 25g PROTEIN.” is not a reasonable reading of the product label. As the images in the 2AC reveal, the quoted statements are disparate phrases that appear vertically arrayed on the label of the 14-ounce RTD bottle and are separated either by additional text or images. *See* 2AC at ¶ 22 (first image).

¹⁴ The same problem limits Plaintiff’s alleged reliance on CytoSport’s television advertisements. She alleges that these advertisements “republish” the “healthy, sustained energy” claim by showing an image of the 14-ounce bottle. 2AC ¶¶ 30-31. Plaintiff further alleges that she “saw

Moreover, the 1AC alleges that 14 ounce bottles containing the “healthy, sustained energy” phrase were phased out beginning in February 2011. 2AC at ¶ 22. Plaintiff admits that she only began purchasing Muscle Milk® RTD in “*approximately February 2011*”—the same time as when she alleges that the label change occurred. *Id.* at ¶ 73. Indeed, Plaintiff did not even allege in the 1AC that she purchased Muscle Milk® RTD with the words “healthy sustained energy” on the label. *See* 1AC at ¶¶ 16-18. Simply put, Plaintiff’s allegations that she relied on the “healthy, sustained energy” statement because it was material to her are the sort of conclusory, unsupported allegations that cannot survive a motion to dismiss in Federal court. *See Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 555; *Cattie v. Wal-Mart Stores, Inc.*, 504 F. Supp. 2d 939, 947-49 (S.D. Cal. 2007).

Plaintiff’s allegations that she relied on statements on CytoSport’s website are also not plausible and do not satisfy Rule 9(b). This Court previously dismissed Plaintiff’s allegations that she relied on such statements. Dkt. 34 at 19:1-3. To cure this, Plaintiff responds with the conclusory allegation that she “visited Cytosport’s website, and she saw and relied on the representations Cytosport made on its website, as discussed above” and that “[t]hese representations were material to her.” 2AC at ¶ 76; *see also id.* (making same allegation regarding television commercials). But Plaintiff alleges no details, such as *when* she visited the website and what, specifically, she viewed. Nor does she allege how often she visited CytoSport’s website. Nor does Plaintiff supply any similar allegations concerning CytoSport’s allegedly misleading television commercials. This paucity of specific allegations is insufficient under Rule 9(b). *See Kearns*, 567 F.3d at 1126; *see also Twombly*, 550 U.S. at 570.

Further, Plaintiff has not alleged that she relied on the allegedly misstated nutrition label on the Vanilla Toffee Muscle Milk® Bar at all, *see* 2AC ¶ 74 (making no mention of this product), nor

and relied [on] Cytosport’s television advertisements, as discussed above These representations were material to her.” *Id.* at ¶ 76. Yet, again, despite including allegations in the 1AC about television advertising (*see* 1AC at ¶ 5 n.1), Plaintiff alleged nothing in the 1AC about television advertising containing the “healthy, sustained energy” phrase with respect to the 14 ounce RTD. Again, Plaintiff cannot credibly allege that these advertisements were material and she relied on them when she did not believe them important enough to even include in the 1AC. Nor is it plausible that Plaintiff materially relied on the small print on the label of a product shown on television.

1 does she even allege that she purchased this particular flavor of bar, *see id.* at ¶ 73 (“Plaintiff
2 regularly purchased . . . Muscle Milk® Bars”).

3 Finally, Plaintiff again fails to articulate “exposure to a long-term advertising campaign” that
4 would relieve her from pleading “individualized reliance on specific misrepresentations.” *In re*
5 *Tobacco II Cases*, 46 Cal. 4th at 328. After taking judicial notice of the same declaration on which
6 Plaintiff bases her new allegations, the Court ruled that Plaintiff “failed to allege that Defendant’s
7 advertising campaign approached the longevity and pervasiveness of the marketing at issue in
8 *Tobacco II.*” Dkt. 34 at 6 n.1, 18:24-27. Plaintiff’s new allegations do not change this conclusion.
9 She claims that CytoSport has sold Muscle Milk® RTD for approximately seven years (since
10 2004)—the very same amount of time that has been deemed to “pale[] in comparison to the decades-
11 long, national, ubiquitous advertising campaigns embarked upon by cigarette manufacturers.” *In re*
12 *Actimmune*, 2009 WL 3740648, at *13. Further, Plaintiff claims that CytoSport has spent \$100
13 million “promoting the Muscle Milk® brand generally,” and has “used a consistent look and feel in
14 the promotion and sale of its Muscle Milk® products.” 2AC at ¶¶ 15, 17 (internal quotation marks
15 omitted). But, even taking these allegations at face value, they are about advertizing for “the Muscle
16 Milk® brand *generally*,” 2AC at ¶ 15 (emphasis added), and Plaintiff has not alleged any facts
17 concerning how much CytoSport spent disseminating the specific advertising statements at issue in
18 this case. By Plaintiff’s logic, a business has engaged in a long-term advertising campaign any time
19 that it advertises a product for any duration in a consistent manner. This is far beyond what the
20 *Tobacco II* court was considering when it addressed a multi-company advertising campaign that
21 “spanned decades.” 46 Cal. 4th at 307.

22 ///

23 ///

24 ///

25 ///

26 ///

27 ///

28 ///

IV. CONCLUSION

The 2AC again rests on the theory that CytoSport has deceived and mislead consumers. Despite being given another opportunity to articulate how CytoSport has done so, Plaintiff has again demonstrated that she cannot allege facts in support of her theory. There is no cognizable cause of action under which Plaintiff may recover. CytoSport respectfully requests that its motion to dismiss the 2AC be granted.

DATED: May 2, 2012

GIBSON, DUNN & CRUTCHER LLP
G. CHARLES NIERLICH
TIMOTHY LOOSE
MATTHEW L. BERDE

By: /s/ G. Charles Nierlich
G. Charles Nierlich

Attorneys for Defendant CytoSport, Inc.